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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,912	03/31/2004	Francis Blanche	08888.0517-01	5703

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,912	BLANCHE ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/970,663.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 10-21 are pending.

Election/Restrictions

Applicant's election with traverse of species in the reply filed on 1/10/06 is acknowledged. The traversal is on the ground(s) that there is no undue burden to search the non-elected species because they were searched in the parent application. This is not found persuasive because undue burden is not a criteria for making a species election. Furthermore, the claims in the parent case were narrower than the instant claims.

The requirement is still deemed proper and is therefore made FINAL.

Hepes and a strong base in claim 15 and sugar and alcohol in claim 18 and claims 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/06.

Priority

The status of the parent application on page 1 of the instant specification needs updated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-12 and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (US 2002/0031527). Wu teaches a method for the preparation of a long-term storage stable adenovirus liquid formulation, comprising the steps of provides an adenovirus and combining said adenovirus with a solution comprising a buffer and a polyol (glycerol), whereby said adenovirus liquid formulation retains high infectivity (page 29). The buffer used for preparing the freeze-dried adenovirus formulation is Tri-HCl (page 3). Wu further teaches a method for the preparation of a long-term, storage stable adenovirus formulation, comprising the steps of providing adenovirus with a solution comprising a buffer, a bulking agent, a cryoprotectant and a lyoprotectant; and lyophilizing the solution, whereby lyophilization of the solution produces a freeze-dried cake of the adenovirus formulations that retains high infectivity and low residual moisture (page 2). Wu teaches the limitation in instant claims 11 and 12 (page 1). The list of bulking agents, cryoprotectant and lyoprotectant are on pages 2-3. The composition for preserving adenoviral particles taught by Wu does not have to have added divalent metal cations or alkali metal cations. Buffering agents and other types of pH control can also be added simultaneously in order to provide for maximum buffering capacity for the adenovirus formulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 2002/0031527) taken with (Sene et al., US Patent No. 6,451,256). Wu teaches a method for the preparation of a long-term storage stable adenovirus liquid formulation, comprising the steps of provides an adenovirus and combining said adenovirus with a solution

comprising a buffer and a polyol (glycerol), whereby said adenovirus liquid formulation retains high infectivity (page 29). The buffer used for preparing the freeze-dried adenovirus formulation is Tri-HCl (page 3). Wu further teaches a method for the preparation of a long-term, storage stable adenovirus formulation, comprising the steps of providing adenovirus with a solution comprising a buffer, a bulking agent, a cryoprotectant and a lyoprotectant; and lyophilizing the solution, whereby lyophilization of the solution produces a freeze-dried cake of the adenovirus formulations that retains high infectivity and low residual moisture (page 2). The list of bulking agents, cryoprotectant and lyoprotectant are on pages 2-3. The composition for preserving adenoviral particles taught by Wu does not have added divalent metal cations or alkali metal cations. Buffering agents and other types of pH control can also be added simultaneously in order to provide for maximum buffering capacity for the adenovirus formulation. For example, pH changes that deviate from physiological conditions often result in irreversible aggregation of proteins (Wetzel, 1992) and viral capsids (Misselwitz et al., 1995) due to complete or partial denaturation of the protein. Thus, buffering agents are particularly important for virus preparations that aggregate or denature at sub-optimal pH ranges. However, Wu does not teach specifically teach a composition comprising adenovirus particles and a buffer solution that maintains the pH of said composition between 8.0 and 9.6 and glycerol.

However, at the time the invention was made, Sene teaches that a Tris buffer solution for preserving recombinant virus particles in frozen or liquid form (abstract). Sene teaches that the infectious viruses gain stability when the aqueous solution used has a basic pH between 8 and 9, preferably 8.5 (column 3). The pH of the buffer is about 8 to 9, preferably 8.5 (column 3-4 and 6-12).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the inventions was made to combine the work of Wu taken with Sene to produce comprising adenovirus particles, glycerol, and a buffer with a pH of 8-9. One of ordinary skill in the art would have been motivated to use the buffer at in the specific pH range taught by Sene because of the gain in stability of the viruses when the solution used has a basic pH.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-12 and 15-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 13-15 of U.S. Patent No. 6,743,008. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both sets of claims are directed to a composition comprising an adenovirus, a buffer solution, glycerol, wherein the buffer does not contain added divalent metal cations or alkali metal cations. The limitation in instant claims 11 and 12 is recited in claims 14 and 15 of '008. The limitation in instant claims 15 and 16 is recited in claim 5 and 6 of '008. The limitation in instant claims 17-19 is recited in instant claims 7-9 of '008.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 13 and 14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3 of prior U.S. Patent No. 6,734,008. This is a double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635